

**Remarks**

Attorney for the Applicants is appreciative of the thoroughness with which Examiner Barrett prepared the February 28, 2003 Office Action. By present amendment, Applicants have amended claims 4, 19, 39 and 42; cancelled claims 40 and 43; and re-presented claims 64-68 (formerly independent claims 8, 25, 55, 57 and 58). Consequently, as result of the foregoing amendments, claims 1-12, 16-21, 23-39, 41-42 and 44-68 are now pending in the present application.

In the February 28, 2003 Office Action, claims 1-7, 9-12, 16-17, 23-24, 39-54, and 56 were rejected as being anticipated by Peredo; claims 16, 18-19, 20-21, 23, 33, 38, 59-63 were rejected as being anticipated by Ionescu et al.; claims 34 and 36-37 were rejected as being unpatentable over Ionescu in view of Love; and claim 35 was rejected as being unpatentable over Ionescu in view of Peredo. Applicants traverse these rejections as set forth below.

I. Claim Rejections – 35 U.S.C. § 112

Claims 4 and 19 have been amended responsive to the Examiner's comments. Claim 4 has been amended to provide sufficient antecedent basis for "a corresponding leaflet." Claim 19 has been amended to provide sufficient antecedent basis for "a line adjacent the out-flow edges of the leaflet." It is believed that, as amended, claims 4 and 19 comply with 35 U.S.C. § 112.

II. Claim Rejections – 35 U.S.C. § 102

A. Peredo Does Not Disclose Or Otherwise Teach The Limitations Of The Claims

Claims 1-7, 9-12, 16-17, 23-24, 39-54, and 56 were rejected by the Examiner under 35 U.S.C. § 102(b) as anticipated by Peredo (6,254,636 B1). Specifically, the Office Action stated:

Peredo discloses a prosthetic semilunar heart valve comprising a plurality of substantially identical leaflets (11) having tabs (18)

extending outwards from the side edge and beyond the out-flow edge of the leaflets (Fig. 4) and further comprising a scalloped in-flow edge (14) and scalloped out-flow edge in a plane perpendicular to the axis of the stent (Fig. 8). The tab portions of adjacent leaflets are connected to one another by reinforcement material (22) to form commissural attachment tabs that extend beyond the out-flow end of the valve (Fig. 7). The leaflets can be made of equine pericardium (col. 3, lines 36-48).

As will be described below, it is respectfully submitted that there are fundamental differences between the Peredo reference and Applicants' invention.

1. Claims 1-7, 9-12, 16-17, 23-24, and 39-41

Claims 1-7 and 9-12 included the following limitation: "the plurality of leaflets being sewn together along at least a portion of their side edges . . . ." (Emphasis added). Additionally, claims 16-17 and 23-24 included the following limitation: "the leaflets being attached to each other along their side edges. . . ." (Emphasis added). Finally, claims 39 and 41, as amended, include the following limitation: "wherein the inward face portions of the leaflets are attached at the side edges of the leaflets." (Emphasis added).

Specifically, and as explained in Applicants' disclosure beginning on page 12, line 22, "[t]he heart valve 130 comprises three flexible leaflets 132 that are sewn together each along a seam line 134 adjacent to their side edges 136. . . . The side edges of adjacent leaflets are sewn together so that the inner surfaces 138 of the sewn-together leaflets 132 face each other, and the side edges extend generally radially outwardly relative a longitudinal center line  $L_c$  of the valve 130." (Emphasis added).

However, careful review of the Peredo reference, including the identified regions noted in the February 28, 2003 Office Action, reveals that Peredo does not disclose or otherwise teach sewing leaflets together by sewing through the side edges of the leaflets.

Peredo discloses a heart valve where the plurality of leaflets are sewn together with stitches between the central plane of a post, an ear, and a rim strip. The assembly, as outlined in Peredo, recites the formation of commissure tabs wherein the ears of the leaflet are folded flat against the separate post that provides the connection for each ear. The post and ear structure is then covered with a separate rim strip, which is sutured to the post and ear structure.

In detail, Peredo teaches a heart valve that relies upon the addition of the separate post to join the ears of the leaflets and the flat surface of the post and ear structure is stitched through its flat surfaces to interior surface of the separate rim strip. See Peredo at col. 4, lines 15-28:

The leaflets 11A-11C are held together at each commissure with a separate commissural post 22, also preferably made of bovine pericardial tissue, as shown in FIG. 5. Each post 22 has a slit 24 sized to slip over two thicknesses of leaflets at the commissure of two adjoining leaflets. The slit 24 permits sliding a post 22 over the edges of two adjoining leaflets to the interior of the commissural mounting ears 18 of the leaflets. The ears or edge portions 18 are positioned outwardly from the commissure posts and fold flat against the posts 22 on the exterior of the slits 24, as shown in FIG. 7. There are three such posts 22 used when a three-leaflet valve is to be assembled, one at each commissure.  
(Emphasis added).

Additionally, Peredo discloses that the commissure structure is then sewn together by stitching through flat surface of the post and ear to the flat surface of the separate rim strip. See Peredo at col. 5, lines 20-29:

As shown in FIG. 3, the posts of the rim strip are also sutured to the posts and the ears of the leaflets with a suture that overlaps the edges of the rim posts and overlap the commissures to insure there is no leakage. The sutures around the periphery of the commissural posts not only can loop over the edge as shown but can be passed through the ears to insure a seal at the commissure. The rim strip portions are also sutured to the edges of the curved base portions.  
(Emphasis added).

Peredo, therefore, does not disclose sewing the leaflets together along a portion of their side edges. Accordingly, it is respectfully submitted that claims 1-7, 9-12, 16-17, 23-24, and 39-41 are allowable over Peredo.

2. Claims 42-54 and 56

Claims 42-48 recite the following limitation: "folding the tab portions relative to each other to form a commissural tab, the commissural tab being attached to the leaflets along a commissural tab line such that the free ends of the tabs extend outwardly from the line." (Emphasis added). Additionally, claims 49-54 and 56 recite the following limitation: "said neck portion being at least substantially unattached along said neck line." (Emphasis added).

Peredo, however, does not disclose free ends of tabs that extend outwardly from the commissural line. Moreover, Peredo specifically teaches a structure wherein the tabs do not extend outwardly in any manner. Instead, the tabs in the Peredo reference are sutured in such a way that there are no free ends of the tabs to extend in any direction. As noted above, the tabs in the Peredo reference are positioned to lay flat against the post, and then they are sutured in the flat position to the rim strip. This does not allow the tabs to have a free end, nor permit any portion of the tab to extend to outwardly.

Peredo, therefore, does not disclose free ends of tabs that extend outwardly from the commissural line. Accordingly, it is respectfully submitted that claims 42-54 and 56 are allowable over Peredo.

B. Ionescu Does Not Disclose Or Teach The Limitations Of The Claims

1. Claims 16, 18-21, 23, 33 and 38

Claims 16, 18-21, and 23 included the following limitation: "wherein the tab portions of adjacent leaflets engage each other to form commissural attachment tabs, at least a portion of each commissural attachment tab being adjacent the outer faces of the adjacent leaflets."

(Emphasis added). Additionally, claims 33 and 38 include the following limitation: "tab portions adjacent the distal end and tending from the side edges." (Emphasis added).

In detail, and as explained in Applicants' disclosure beginning on page 13, line 11, "[t]he commissural tabs 150 are dedicated to providing commissural attachment sites that are isolated from the folding leaflets 132 in order to improve durability and to provide an easy, visible target for the surgeon to place commissural sutures when implanting the valve."

Additionally, the leaflets include commissural tabs that are formed from the leaflet material. Specifically, and as stated in Applicants' disclosure on page 13, line 16: "a tab portion 154 of adjacent leaflets 132 between the seam line 134 and the side edge 136 are extended somewhat in a distal portion of the valve 130A. The extended portions of 152 are folded back so as to be generally parallel the outer face 140 of the corresponding leaflet 132. This results in a pair of tab portions 152 that extend behind the valve and substantially tangential to the open valve. Each of the tabs 152 can be connected to the aortic wall by a suture 154." (Emphasis added).

Continuing on line 26, "an additional embodiment of a dedicated commissural tab 160 comprises a raised portion of 162 of the leaflets 132 positioned adjacent the seam line 134 and extending distally from the distal end of the adjacent leaflets." (Emphasis added).

By comparison, the Ionescu reference, including the identified regions noted in the February 28, 2003 Office Action, reveals that Ionescu does not disclose or otherwise teach that adjacent leaflets engage each other to form commissural attachment tabs. In fact, Ionescu discloses a seam line where the adjacent leaflets join, but there are no structures included in the leaflets that form or operate as commissural tabs.

The Examiner asserts that the tabs are formed where the adjacent leaflets overlap, but the Ionescu disclosure does not support this proposition. In fact, Ionescu provides an additional structure, separate and apart from the leaflets – the pledget – to serve as a tab for the attachment of the valve to the interior anatomy of the aorta or ventricle. See Ionescu at col. 8, lines 54-58.

Moreover, the disclosure of Ionescu teaches away from the concept that the commissural tabs can be formed and contained within the leaflets by stating: "[i]t is neither necessary nor possible to give exact shape and dimensional definitions to the leaflets exemplified by leaflet 30." Ionescu at col. 6, lines 53-58.

Ionescu, therefore, does not disclose tab portions of adjacent leaflets that engage each other to form commissural attachment tabs. Accordingly, it is respectfully submitted that claims 16, 18-21, 23, 33 and 38 are allowable over Ionescu.

2. Claims 59-63

Claims 59-63 include the following limitation: "said annulus having a periphery comprised of edges which are scalloped." (Emphasis added). As Applicants' disclosure explains, at page 15, starting at line 3, "Applicants have determined that scalloping both the inflow and outflow edges 172, 174 of each leaflet helps to maximize the valve's hemodynamic

performance and to minimize creasing and folding, which may have long term, negative effects on valve durability, as well as closure capability."

Additionally, Applicants' disclosure states that the leaflets, and the scalloping of the leaflets for particular embodiments, should be completed according to specified dimensions:

[a]s can be seen in Figures 8 and 9, the scalloping adjacent the inflow annulus 176 is such that the center portion of the leaflet extends proximally beyond the proximal end of the leaflet adjacent the seam line 178. The distance  $D_p$  between the proximal end 172 of each leaflet at a point adjacent the seam line 178 and at the center of the leaflet has been determined through testing to preferably be between about 15%-25% of the overall diameter of the valve, and most preferably about 20% of the diameter of the valve. The scalloping shape preferably follows a smooth curve.

At the distal end 174 of the valve, the center portion of each leaflet is preferably positioned a distance  $D_d$  proximal of the distal end of the leaflets adjacent the seam line 178. This distance  $D_d$  has been determined through testing to be preferably between about 8%-20% of the overall diameter of the valve, and is more preferably between about 15%-17% of the diameter of the valve. As with the inflow annulus, the scalloping out shape preferably follows a smooth curve. See Applicants' disclosure at page 15, lines 8-20.

Ionescu, by comparison, specifically teaches that the cutting of the leaflets, and any shape associated with the leaflets, need not be made to specific dimensions. See Ionescu at col. 6, lines 7-12. Moreover, the Ionescu reference teaches a pattern that contains a truncated cone configuration (see Ionescu Fig. 5), not one that is scalloped in relation to overall diameter of the valve. Additionally, the leaflet pattern disclosed in the Ionescu reference is a pattern where "it is neither necessary nor possible to give exact shape and dimensional definitions to the leaflets exemplified by leaflet 30." See Ionescu at col. 6, lines 53-58.

Ionescu, therefore, does not disclose leaflets that are scalloped on the peripheral edge. Consequently, it is respectfully submitted that claims 59-63 are allowable over Ionescu.

III. Claim Rejections – 35 U.S.C. § 103

Claims 34 and 36-37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al. (4,388,735) in view of Love et al. (5,163,955) as cited in Applicants' IDS.

Specifically, the Office Action stated:

Ionescu et al. discloses a prosthetic valve comprising leaflets however Ionescu et al. fails to disclose the leaflets as being laser cut pericardium. Love et al. teaches the use of laser cut pericardium, which can be computer controlled and therefore more precision (col. 24, lines 15-30). It would have been obvious to one of ordinary skill in the art to combine the teaching of use of laser cut pericardium, as taught by Love et al., to a prosthetic valve comprising leaflets as per Ionescu et al., in order to have computer controlled cuts and therefore more precision.

1. Claims 34 and 36-37

Claims 34 and 36-37 depend from claim 33. Accordingly, all the limitations contained in claim 33 are included in claims 34 and 36-37. As discussed above, Ionescu does not anticipate claim 33 because the reference does not disclose each limitation in the claim. Specifically, claims 33 includes the following limitation: "tab portions adjacent the distal end and tending from the side edges," which is not disclosed in the Ionescu reference.

Therefore, inasmuch as the Examiner cites Ionescu as being obvious with Love to disclose making precise cuts of pericardium tissue using a laser, the combination of these two references does not disclose all of the limitations contained in claim 33.

Specifically, the combination of these two claims does not disclose a "tab portion adjacent the distal end tending from side edges." In fact, the Ionescu reference does not disclose a tab portion as part of the leaflet. Thus, using a laser to cut the Ionescu leaflet does not disclose



a tab as part of the leaflet. Furthermore, the cutting of the leaflet using a non-contact cutting apparatus, such as a laser, does not disclose a leaflet with a tab.

Accordingly, it is respectfully submitted that claims 34 and 36-37 are allowable over Ionescu in view of Love.

2. Claim 35

Claims 35 was rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al. (4,388,735) in view of Peredo (6,254,636 B1). Specifically, the Office Action stated:

Ionescu et al. discloses a prosthetic valve comprising leaflets however Ionescu et al. fails to disclose the leaflets as being equine pericardium. Peredo teaches the use of equine pericardium (col. 3, lines 36-48), which is widely available and lower in cost. It would have been obvious to one of ordinary skill in the art to combine the teaching of use of equine pericardium, as taught by Peredo, to a prosthetic valve comprising leaflets as per Ionescu et al., because of its availability and lower cost.

Claims 35 depends from claim 33. Accordingly, all the limitations contained in claim 33 are included in this claim. As discussed above, Ionescu does not anticipate claim 33 because the reference does not disclose each limitation in the claim. Specifically, claims 33 includes the following limitation: "tab portions adjacent the distal end and tending from the side edges," which is not disclosed in the Ionescu reference.

Thus, even though the Examiner cites Ionescu as being obvious with Peredo to disclose making leaflets from equine pericardium, the combination of these two references does not disclose all of the limitations contained in claim 33. Additionally, the combination of these two claims does not disclose a "tab portion adjacent the distal end tending from side edges." In fact, the Ionescu reference does not disclose a tab portion as part of the leaflet. Thus, using an equine

pericardium to make the leaflet disclosed in the Ionescu reference does not disclose a leaflet that contains a tab as part of the leaflet, regardless of the material used to make the leaflet.

Accordingly, it is respectfully submitted that claim 35 is allowable over Ionescu in view of Peredo.

IV. Allowable Subject Matter

The Examiner has suggested that claims 8, 25, 55 and 57-58 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants submit claims 64-68 as re-presented claims of former dependent claims 8, 25, 55 and 57-58. It is believed that, as re-presented, claims 64-68 are presently allowable.

Conclusion

In light of the foregoing amendments and remarks, all of the claims pending in this application are believed to be patentable over the art of record. Thus, Applicants respectfully ask the Examiner to favorably consider the claims and issue a notice of allowance.

Respectfully submitted,

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Dated: May 28, 2003

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